UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
TEXARKANA DIVISION

UNITED STATES OF AMERICA *ex rel.* HEALTH CHOICE ADVOCATES, *et al.*,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 5:17-cv-00121-RWS-CMC
GILEAD SCIENCES, INC., *et al.*,	)	
Defendants.	)	

DEFENDANT COVANCE INC.'S MOTION TO DISMISS

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Pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6), Defendant Covance Inc. ("Covance") respectfully moves the Court to dismiss the First Amended Complaint filed by Relators Health Choice Advocates, LLC ("HCA, LLC") and Jaime Green (collectively, "Relators").

INTRODUCTION

Health insurance is complex. Patients must often understand multiple layers of benefits and coverage for prescribed medications. Pursuant to contracts with drug manufacturers, Covance helps patients navigate those health insurance benefits, including verifying patients have insurance coverage for the medicine prescribed. Relators—led by a New Jersey limited liability company formed specifically to bring this lawsuit—try to turn this legitimate patient service into a federal fraud case. Relators theorize that Covance and Gilead Sciences, Inc. ("Gilead") somehow violated the federal Anti-Kickback Statute ("AKS") by offering these common support services to induce doctors to prescribe Gilead's drugs. They then speculate that these alleged AKS violations caused the submission of false claims to the government, as prohibited by the federal False Claims Act ("FCA") and state analogues. Notably, while Relators attempt to assert two additional theories against other Defendants, they do not involve Covance in either of them. The Court should dismiss the attenuated claims against Covance for at least three reasons.

First, the Amended Complaint fails to plead a required element for an AKS violation: that Covance provided "remuneration." The Office of Inspector General ("OIG") for the Department of Health and Human Services has concluded that patient support services like those Relators allege "do not implicate" the AKS. Covance's alleged support services are integrally related to the provision of Gilead's medications and they have no substantial independent value apart from those drugs. Thus, they are not prohibited "remuneration." Because Relators fail to allege an AKS violation, they fail to state an FCA claim.

Second, Relators are not true whistleblowers. The FCA's "public disclosure bar" prohibits *qui tam* claims where the material facts were publicly disclosed. Here, anyone could search the internet and make the same allegations Relators raise by using public information, primarily from the websites of Covance and a public news source. And while the public disclosure bar includes an exception for "original sources" of information, Relators do not qualify. The FCA's *qui tam* provision is intended to encourage insiders with unique knowledge to bring fraud to light—not to provide a windfall to those who fashion FCA claims using information that is already available to the government and the general public.

Third, the Amended Complaint fails under Fed. R. Civ. P. 9(b) because it does not plead its claims with particularity. Relators fail to describe the "who, what, when, where, and how" for any alleged FCA violation, as required under Rule 9(b). The Amended Complaint does not specify doctors whose judgment allegedly was affected by the provision of support services, which patients reportedly received prescriptions, which drugs they received, whether they were on government insurance programs, which pharmacies filled prescriptions, or which insurance programs paid for prescriptions, among other things. Rather, Relators simply summarize how government insurance programs work and leap to the conclusion that false claims were submitted. Given the lack of specifics, the Amended Complaint fails to satisfy Rule 9(b).

Beyond those fatal flaws, certain counts suffer from additional deficiencies that independently require dismissal. For instance, Relators allege that Covance violated Medicare regulations, but those regulations have nothing to do with the FCA, and regardless Relators fail to allege any wrongdoing. In addition, Relators bring state-law counts, but some of these state false claims statutes do not even permit *qui tam* enforcement. Lastly, Relators bring a claim for conspiracy, but fail to allege an agreement to violate the FCA.

For these reasons, and as explained below, the Court should dismiss Relators' claims against Covance.

STATEMENT OF ISSUES

1. Whether the Amended Complaint alleges that Covance provided "remuneration" under the AKS, despite OIG guidance indicating that support services do not violate the AKS.
2. Whether the FCA's public disclosure bar precludes Relators' claims, which are substantially similar to publicly disclosed information.
3. Whether the Amended Complaint meets Rule 9(b)'s particularity standard as to Covance when it vaguely alleges a broad fraudulent scheme and assumes, with no examples or reliable evidence, that false claims were submitted to the government for payment.
4. Whether the Amended Complaint states a claim regarding alleged violations of Medicare regulations when the regulations do not relate to the False Claims Act and, regardless, Relators fail to allege with particularity that Covance violated the regulations.
5. Whether the Amended Complaint states a claim under thirty-one separate states' false claims statutes when some state statutes do not permit Relators to bring *qui tam* actions and, regardless, the state-law counts mirror the federal counts.
6. Whether the Amended Complaint states a claim for conspiracy when it fails to allege facts showing Covance entered into an agreement to violate the AKS and the FCA.

FACTUAL AND LEGAL BACKGROUND

I. Procedural History

HCA, LLC filed its Complaint under seal pursuant to the FCA, 31 U.S.C. § 3729 *et seq.*, on June 14, 2017. Dkt. 1. The Complaint remained under seal while the United States and the named states investigated. On October 30, 2017, the federal government and all thirty-one named states declined to intervene. Dkt. 8. Unfazed, HCA, LLC chose to proceed on a *qui tam*

basis and served Defendants after the Court ordered the Complaint unsealed on October 31.[1] Dkt. 9. On January 12, 2018, Relators filed the Amended Complaint, adding Green as a relator. Dkt. 53. Covance now moves to dismiss the claims against it.

II. Relators' Theory

Relators generally allege that Covance was part of a "multi-tiered kickback scheme." First Am. Compl., Dkt. 53 ¶ 1 ("Amended Complaint" or "FAC"). Although the Amended Complaint asserts theories against Gilead, Covance, HealthSTAR Clinical Education Solutions LLC ("Healthstar"), Aerotek, Inc. ("Aerotek"), and Randstad Healthcare ("Randstad") (collectively, "Defendants"), *id.*, the allegations against Covance center on it and Gilead. *See* FAC ¶¶ 125-51. The Amended Complaint focuses on four Gilead medications: Sovaldi, Harvoni, Truvada, and Atripla (the "Covered Drugs"). FAC ¶ 2. Sovaldi and Harvoni are used to treat patients with Hepatitis C, and Truvada and Atripla to treat patients with HIV-1.

A. Background

Relators allege that Gilead, "with substantial assistance from" the other Defendants, engaged in three fraudulent schemes. FAC ¶ 3. In "Scheme One," Relators allege that Gilead, through Healthstar, used "nurse educators" as "undercover sales representatives" to recommend Sovaldi and Harvoni to doctors ("Prescribers"). FAC ¶ 4. In "Scheme Two," Relators allege that Gilead, with assistance from Covance, Aerotek, and Randstad, "provided in-kind remuneration to Prescribers in the form of reimbursement support services" "to induce

[1] Two other related LLCs have brought related *qui tam* actions against other pharmaceutical companies and the entities who allegedly helped market their drugs, raising the same causes of action Relators bring here. HCA, LLC and the LLC relators in those cases all claim to be affiliated with the same research organization in New Jersey, and the same counsel represent relators in all three cases. *See* FAC ¶ 24; First Am. Compl. ¶ 22, *Health Choice Alliance v. Eli Lilly & Co.*, No. 5:17-cv-00123 (E.D. Tex. Jan. 12, 2018), ECF No. 42; First Am. Compl. ¶¶ 26-27, *Health Choice Grp. v. Bayer Corp.*, No. 5:17-cv-00126 (E.D. Tex. Jan. 12, 2018) (also adding Green as a relator), ECF No. 32.

Prescribers to prescribe the Covered Drugs to their patients." FAC ¶ 5. In "Scheme Three," Relators allege that Gilead, "with assistance from Healthstar," "provided in-kind remuneration to Prescribers in the form of free nursing services in part to induce them to prescribe Sovaldi and Harvoni." FAC ¶ 6. Relators' material allegations implicate Covance only in "Scheme Two."

Relators contend that, through these broadly described "schemes," Defendants violated the Anti-Kickback Statute, and therefore the False Claims Act, by (1) causing false and fraudulent claims to be presented to federal health care programs for payment (Count 1); (2) causing pharmacies and other entities to falsely certify they were complying with the AKS and other state and federal laws (Count 2); and (3) conspiring to violate the FCA (Count 3). *See* FAC ¶¶ 200-15 (citing False Claims Act, 31 U.S.C. § 3729(a)(1)(A)-(C)). Relators also allege that Defendants violated FCA analogues from thirty-one states (Counts 4-34). FAC ¶¶ 216-370.

B. The Anti-Kickback Statute

The Anti-Kickback Statute is a federal criminal statute that prohibits "knowingly and willfully" offering "remuneration . . . to induce" someone "to refer an individual . . . for . . . any item or service" reimbursable under a federal health care program. 42 U.S.C. § 1320a-7b(b)(2)(A). Such conduct is a felony punishable by years in prison and significant fines. *Id.* Neither Covance nor any Covance employee has been charged with violating the AKS in connection with the conduct alleged in the Amended Complaint.

C. The False Claims Act

Relators invoke the federal False Claims Act and state corollaries. The FCA targets those who intentionally deceive the government by "knowingly" presenting or causing to be presented "a false or fraudulent claim" for payment to the United States. 31 U.S.C. § 3729(a)(1)(A). Given its targeted focus and severe punishment—including treble damages and thousands per false claim in civil penalties—the FCA is not "'an all-purpose antifraud statute'" or "a vehicle

for punishing garden-variety . . . regulatory violations." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016) (citation omitted). Rather, it is a unique "punitive" statute that allows an individual to bring suit on the government's behalf against only those who knowingly and intentionally defraud the government in connection with a false claim for payment. *U.S. ex rel. Steury v. Cardinal Health, Inc*., 625 F.3d 262, 268 (5th Cir. 2010).

D. Covance's Provision Of Support Services

In the one purported scheme that implicates Covance, Relators allege Covance provided three services for Gilead's drugs. FAC ¶ 126. First, Covance provided "benefit verification[]" services, contacting insurers to verify a patient's medication coverage. FAC ¶ 140. Second, Covance provided "prior authorization services," helping confirm pre-approval from insurers before a doctor prescribed Gilead's drugs. FAC ¶ 141. Third, Covance offered services to help "appeal authorization and coverage denials." FAC ¶ 142. Relators rely upon Covance's website in making these factual allegations. *See* FAC ¶ 21 & nn.11-12.

Relators allege that, without these services, doctors would have had to perform patients' benefit verification, prior authorization, and coverage appeals on their own. FAC ¶ 145. According to Relators, Gilead and Covance used support services to "induce recommendations of the Covered Drugs over competing drugs." FAC ¶ 125. From these basic assertions, Relators leap to the conclusion that Gilead and Covance violated the AKS. FAC ¶ 145. Relators then go further, theorizing that these purported violations must have caused the submission of false claims to the government for payment in violation of the federal False Claims Act. FAC ¶ 182.

Despite its wide-ranging theory of fraud, the Amended Complaint provides little meaningful detail. It does not allege that Covance provided anything other than mere support services, or that they differed from those previously authorized by the OIG. It does not identify any patient who filled a prescription, which pharmacy filled it, or any details regarding requests

for payment to government programs. It lists two unnamed prescribers who allegedly used unspecified services for unnamed patients, FAC ¶ 183, but these prescribers do not provide additional details. Ultimately, Relators broadly describe an alleged fraudulent scheme, then summarily conclude that claims submitted for Gilead's products "stemmed from prescriptions that were tainted by kickbacks" and "would be submitted to [government] programs," FAC ¶ 83.

Lacking specifics, Relators rely on conclusory allegations. They cite purported current and former employees of the Defendants, but these "Confidential Interviewees" ("CIs") did not provide the absent details. They merely "confirmed" that Covance offered support services. *See, e.g.*, FAC ¶¶ 134, 138. Relators summarily claim that Scheme Two encompassed "every Prescriber that, since at least 2013, received Support Services from Covance." FAC ¶ 179. They then contend that Covance and Gilead "caused pharmacies [and other entities] to submit millions of dollars in claims to Government programs for Gilead drugs provided to beneficiaries as a result of [their] illegal marketing and quid pro quo arrangements." FAC ¶ 182. And Relators reproduce publicly available summary data on Medicare claims for Gilead's drugs, FAC ¶¶ 185-99, but do not allege or explain which (if any) claims resulted from allegedly illegal kickbacks.

Finally, Relators allege that Gilead and Covance violated Medicare regulations by contacting federal insurers to obtain coverage determinations for patients. FAC ¶¶ 146-51. Relators do not explain how these alleged statements violated the AKS or the FCA.

APPLICABLE PLEADING STANDARDS

Under Fed. R. Civ. P. 12(b)(6), a court must dismiss a complaint if it does not allege facts that, when "accepted as true . . . 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The plaintiff may not offer mere "'labels and conclusions,'" nor give a "'formulaic recitation of the elements of a cause of action,'" nor show "a sheer possibility that a defendant has acted

unlawfully." *Id.* Rather, the plaintiff must plead sufficient "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* The court need not accept legal conclusions or bald assertions. *Id.* And where, as here, the complaint alleges claims against multiple defendants, the court must consider its adequacy as to each defendant separately. *Sanchez v. Pereira-Castillo*, 590 F.3d 31, 48 (1st Cir. 2009); *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 287 (5th Cir. 2006).

FCA relators also must plead fraud "with particularity." Fed. R. Civ. P. 9(b). Rule 9(b) "serves an important screening function," as it "'provides defendants with fair notice of the plaintiffs' claims, protects defendants from harm to their reputation and goodwill, reduces the number of strike suits, and prevents plaintiffs from filing baseless claims then attempting to discover unknown wrongs.'" *Melder v. Morris*, 27 F.3d 1097, 1100 (5th Cir. 1994) (citation omitted). This heightened standard "is especially important in light of the quasi-criminal nature of FCA violations." *U.S. ex rel. Atkins v. McInteer*, 470 F.3d 1350, 1360 (11th Cir. 2006).

ARGUMENT

Even accepting the Amended Complaint's factual allegations, the Court should dismiss its claims against Covance because it (1) fails to allege a violation of the Anti-Kickback Statute; (2) triggers the False Claims Act's public disclosure bar; and (3) fails to plead fraud with particularity under Rule 9(b). Each argument independently warrants dismissal of Counts 1, 2, and 3, which attempt to assert AKS and FCA violations. Further, the Court should dismiss any claims for alleged Medicare regulatory violations, as Relators lack standing to bring them and fail to allege any wrongdoing; dismiss the state-law Counts (4-34), as Relators lack standing to bring certain counts, and they all fail for the same reasons as the federal counts; and dismiss Count 3 for the independent reason that Relators fail to plead a conspiracy.

I. Relators Fail To Plead A Violation Of The Anti-Kickback Statute

Fundamentally, Relators fail to plead an essential element for an AKS violation: that Covance "knowingly and willfully" gave "remuneration" (i.e., the "kickback") to induce doctors to prescribe federally reimbursable medications. 42 U.S.C. § 1320a-7b(b)(2).

A. Covance Did Not Provide Remuneration

Where a defendant does not give or receive remuneration, it does not violate the AKS. *See U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 894 (5th Cir. 2013) (affirming dismissal where complaint did not sufficiently "allege, nor reliably indicate" that the defendant provided "remuneration" to referring physicians); *U.S. ex rel. Conner v. Salina Reg'l Health Ctr., Inc.*, 543 F.3d 1211, 1223 (10th Cir. 2008) (affirming dismissal of FCA claims "because [Relator] has not alleged a kickback within the meaning of the Anti-kickback statute").

Because of the continually evolving nature of the health care industry, the OIG "facilitate[s] the enforcement of" the AKS and other statutes, 42 U.S.C. §§ 1320a-7c, by issuing advisory opinions as to "[w]hat constitutes prohibited remuneration" and "[w]hether an arrangement . . . satisfies the criteria" for certain safe harbors. 42 C.F.R. 1008.5(a)(1)-(2). Notably for purposes of this case, the OIG "has long distinguished" between "items and services that are integrally related to the offering provider's or supplier's services and those that are not." Medicare & State Health Care Programs: Fraud & Abuse; Elec. Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79202, 79210 (Dec. 27, 2013) ("2013 OIG Guidance"). Providing support products or services that lack "substantial independent value" apart from the primary product does not violate the AKS. OIG Compliance Program Guidance for Pharm. Mfrs., 68 Fed. Reg. 23731-01, 23735 (May 5, 2003) ("2003 OIG Guidance"); *see* OIG Op. 12-10, 2012 WL 4753657, at *3 (Aug. 23, 2012); OIG Op. No. 00-10, 2000 WL 35747420, at *4 (Dec. 15, 2000). For instance, a laboratory company can provide "free access"

to a computer system "used only to transmit orders" and "to receive the results of" laboratory tests. Such a service is "integrally related to the donor's services" and lacks independent value, so it is not prohibited "remuneration." 2013 OIG Guidance, 78 Fed. Reg. at 79210; *see* Medicare & State Health Care Programs: Fraud & Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952-01, 35978 (July 29, 1991).

Even more specifically, OIG Guidance provides that pharmaceutical manufacturers may offer "support services in connection with the sale of their products," including "billing assistance tailored to the purchased products [and] reimbursement consultation." 2003 OIG Guidance, 68 Fed. Reg. at 23735. Because these services have no substantial independent value "[s]tanding alone," they do not violate the AKS. *Id.*

This critical rule has led the OIG previously to permit the very support services Relators allege Covance provided, including "pre-qualification of patients for third party coverage and reimbursement" and "reimbursement support services." OIG Op. 00-10, 2000 WL 35757520, at *2. In Opinion 00-10, the OIG found that a drug manufacturer's mere provision of these services did "**not implicate the Federal anti-kickback statute**." *Id.* at *4 (emphasis added). Because the services had "no independent value to providers apart from the products, they [were] properly considered part of the products purchased and their cost [was] already included in the products' price." *Id.* A federal court recently reiterated the point, explaining that "support services that are 'specifically tied to support of the purchased product' standing alone do not implicate the AKS." *U.S. ex rel. Forney v. Medtronic, Inc.*, No. 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017) (quoting 2003 OIG Guidance and granting motion to dismiss).

Given this legal framework, Relators fail to allege that Covance provided remuneration. *See id.* at *4 n.2 (applying 2003 OIG Guidance to determine whether support services were

prohibited "remuneration"). Covance allegedly provided the same "pre-qualification" and "reimbursement support services" the OIG approved in Opinion 00-10, nothing more. *See* 2003 OIG Guidance, 68 Fed. Reg. at 23735. These services had no substantial independent value beyond Gilead's products. Rather, once a doctor decided a patient needed a Gilead medication, Covance merely confirmed that the patient's insurance would cover it.[2] These services, "standing alone," do not violate the AKS. *Id*; OIG Op. 00-10, 2000 WL 35757520, at *2 (same).

Forney confirms that conclusion. There, the relator alleged that the defendant, a medical device manufacturer, violated the AKS and the FCA by offering "free surgical support, implant device follow-up that it continued to offer long after device implantation," "free staff to clinics," and "free assistance on billing its devices to federal health care programs." 2017 WL 2653568, at *1-2. Because the services were offered specifically to support the defendant's products and the relator failed to describe with specificity how the services provided "substantial," "independent value" apart from those products, the court rejected the relator's "novel theory of FCA liability." *Id.* at *3-4. It thus dismissed the relator's AKS-based FCA claim for its failure to allege prohibited "remuneration." *Id.* This Court should likewise do so here.[3]

Because Covance's support services were integrally related to the provision of the prescribed medications and lacked substantial independent value, the Amended Complaint fails

[2] Nor do Relators allege Covance offered anything in tandem with support services, such as a reimbursement guarantee, which the OIG indicated could implicate the AKS. *See id.*

[3] Covance's services also included safeguards the OIG has concluded insulate a program from the AKS. Covance helped address "access problems," especially a prohibitive price tag, for life-saving medicine. *Compare* FAC ¶ 139 (noting that Gilead's drugs can cost $84,000 annually) *with* OIG Op. 00-10, 2000 WL 35747420, at *6-7 (citing access problems where drugs costed $6,000 annually). In addition, Covance's services ran no risk of "overutilization." Federal insurers often required prior authorization, FAC ¶ 141, but that means the government permitted doctors to prescribe Gilead's medications only if it *agreed that the medications were necessary*. *See* OIG Op. 00-10, 2000 WL 35747420, at *5-6 (noting support program did not risk overutilization because it verified that the patient met insurance coverage guidelines and the drug's cost ensured that insurers would limit coverage).

to allege that Covance provided illegal remuneration and fails to plead an AKS violation. With no underlying AKS violation, the Court should dismiss the FCA claims. *U.S. ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 372-76 (5th Cir. 2016) (per curiam) (affirming dismissal of FCA claims because relator failed to show underlying AKS violation).

B. Covance Did Not *Knowingly* Provide Remuneration

Even if Covance were incorrect that its support services were not prohibited "remuneration"—and it is not—Covance's conclusion was not so unreasonable as to make it liable for "knowingly" committing fraud in violation of the FCA.[4] 31 U.S.C. § 3729(a)(1). "For FCA liability to attach, not only must the defendant submit false claims, but the defendant must have '*knowingly* or *recklessly* cheated the government.'" *U.S. ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App'x 366, 371 (5th Cir. 2011) (per curiam) (citation omitted). Yet, as a matter of law, an "FCA defendant does not act 'with the knowledge that the FCA requires before liability can attach' when 'the defendant's interpretation of the applicable law is a reasonable interpretation, perhaps even the most reasonable one.'" *U.S. ex rel. Ketroser v. Mayo Foundation*, 729 F.3d 825, 832 (8th Cir. 2013) (quoting *U.S. ex rel. Hixson v. Health Mgmt. Sys., Inc.*, 613 F.3d 1186, 1190 (8th Cir. 2010)); *see Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007) ("Where, as here, the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.").

As such, even if Relators could show that Covance's support services were remuneration—despite OIG guidance to the contrary—that would not be enough. Because

[4] Indeed, because Relators allege an AKS-based FCA claim, they must prove that Covance "knowingly *and willfully*" provided improper "remuneration." 42 U.S.C. § 1320a-7b(b)(2) (emphasis added).

Covance's conduct complied with a reasonable interpretation of the AKS, the Court should still dismiss for failure to satisfy the FCA's scienter requirement.

II. The FCA's Public Disclosure Bar Precludes Relators' Claims

The Court should also dismiss the claims against Covance for a second, independent reason: the Amended Complaint's allegations come from publicly available information—Covance's and a public news source's websites, no less. The FCA bars *qui tam* actions where "relators bring a suit based on publicly available information." *U.S. ex rel. Jamison v. McKesson Corp.*, 649 F.3d 322, 324 (5th Cir. 2011). More specifically, the "public disclosure bar" requires courts to dismiss FCA claims "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed" "from the news media." 31 U.S.C. § 3730(e)(4)(A)(iii). The bar furthers the FCA's goals by helping to fight fraud while "'preventing parasitic suits by opportunistic late-comers who add nothing to the exposure of fraud.'" *U.S. ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 (5th Cir. 2004) (citation omitted). Indeed, if the operative facts are public, then the relator is not a true whistleblower, as the government "either has notice of the wrongdoing or gains nothing from a relator with indirect knowledge of the same facts." *U.S. ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 373 (5th Cir. 2017). As such, the Fifth Circuit consistently applies the "public disclosure bar" to dismiss FCA claims. *See U.S. ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 327 (5th Cir. 2017); *Jamison*, 649 F.3d at 332; *Reagan*, 384 F.3d at 179-80; *Fed. Recovery Servs., Inc. v. United States*, 72 F.3d 447, 450-52 (5th Cir. 1995).

Courts apply a three-part test to decide whether the public disclosure bar applies: (1) whether there has been a "public disclosure"; (2) whether the lawsuit is substantially similar to the publicly disclosed information; and (3) if so, whether the relator is nevertheless an "original source" of the information. 31 U.S.C. § 3730(e)(4)(A); *Colquitt*, 858 F.3d at 373. Once a party

identifies "public documents that could plausibly contain allegations or transactions upon which the relator's action is based, the relator bears the burden of demonstrating that they do not." *Jamison*, 649 F.3d at 327. All three parts of the test are satisfied here.[5]

A. Relators' Allegations Were Publicly Disclosed

First, the Amended Complaint's allegations were publicly disclosed. Like the public disclosure bar itself, the term "news media" has "'a broa[d] sweep.'" *Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 408 (2011) (citation omitted). Accordingly, "[c]ourts have unanimously interpreted the term 'public disclosure' to include websites and online articles." *Green v. AmerisourceBergen Corp.*, No. 4:15-CV-379, 2017 WL 1209909, at *6 (S.D. Tex. Mar. 31, 2017); *see Osheroff*, 776 F.3d at 813; *U.S. ex rel. Kraxberger v. Kansas City Power & Light Co.*, 756 F.3d 1075, 1079 (8th Cir. 2014).

Various public websites disclosed the same allegations Relators allege in the Amended Complaint. Covance widely advertised on its website the same services alleged in the Amended Complaint: benefit verification, preauthorization services, and help with coverage denials and appeals.[6] The Amended Complaint even quotes Covance's website as support for Relator's

[5]The Fifth Circuit has previously addressed the public disclosure bar as "intertwined with the merits and so properly treated as [a] motion for summary judgment when brought under a motion to dismiss." *Colquitt*, 858 F.3d at 373 (citing *Jamison*, 649 F.3d at 326). Still, when considering a motion to dismiss, "[a] court is permitted . . . to rely on 'documents incorporated into the complaint by reference, and matters of which a court may take judicial notice.'" *Dorsey v. Portfolio Equities, Inc.*, 540 F.3d 333, 338 (5th Cir. 2008) (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007)). Here, the Amended Complaint incorporates Covance's website, which disclosed the material allegations against Covance. *See* FAC ¶ 21 & nn.11-12. It also incorporates ProPublica's website, which disclosed the government's Medicare data. *See* FAC ¶ 185 & n.32. Moreover, courts may take judicial notice of information publicly available online. *See U.S. ex rel. Osheroff v. Humana, Inc.,* 776 F.3d 805, 811–12 (11th Cir. 2015) (affirming district court's consideration of websites and other documents in granting dismissal of the relator's complaint under the public disclosure bar); *Coleman v. Drake*, 409 F.3d 665, 667 (5th Cir. 2005) (taking judicial notice of website); Fed. R. Evid. 201. Thus, this Court may consider the public disclosure bar without converting Covance's motion to a motion for summary judgment.

[6] *See Patient Services and Provider Services*, Covance, www.covance.com/industry-solutions/healthcare/commercialization/patient-and-provider-services.html, attached as Ex. A; *Patient Access Programs*, Covance, www.covance.com/industry-solutions/healthcare/commercialization/patient-

allegations. FAC ¶ 21 & nn.11-12. Similarly, Relators obtained the summary Medicare data from ProPublica's website, an independent news source, so it too was disclosed from the news media. *See* FAC ¶¶ 185-99 & nn.32-36. ProPublica's website even lists hundreds of individuals who prescribe Gilead's drugs. *See, e.g.*, *Harvoni Prescriber Checkup*, ProPublica, projects.propublica.org/checkup/drugs/8393 (last visited Feb. 20, 2018), attached as Ex. F. Thus, Relators' allegations against Covance were publicly disclosed.

B. Relators' Allegations Are Substantially Similar To The Public Disclosures

Second, "substantially the same allegations or transactions" as alleged in the action were "publicly disclosed" here.[7] *Id.* For the second part of the test, the public information need not allege wrongdoing. *Osheroff*, 776 F.3d at 814. It need not cover every allegation in the complaint. *See U.S. ex rel. Fried v. W. Indep. Sch. Dist.*, 527 F.3d 439, 442 (5th Cir. 2008). Nor must it "name particular defendants," so long as it "'alerted the government'" to the "'nature of the fraud and enabled the government to readily identify wrongdoers through an investigation.'" *Jamison*, 649 F.3d at 329 (citation omitted). It is sufficient if "'one could have produced the substance of the complaint merely by synthesizing the public disclosures' description of the [fraudulent] scheme.'" *U.S. ex rel. Solomon v. Lockheed Martin Corp.*, 878 F.3d 139, 144 (5th

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and-provider-services/patient-access-programs.html, attached as Ex. B; *Patient Support*, Covance, www.covance.com/services/health-economics-and-market-access/patient-support.html, attached as Ex. C; *Field Services*, Covance, www.covance.com/services/health-economics-and-market-access/field-services.html, attached as Ex. D; *Covance Patient and Provider Services*, https://www.covance.com/content/dam/covance/assetLibrary/brochures/PPS-Brochure-BROCMA009.pdf, attached as Ex. E (all last visited Feb. 20, 2018).

[7] The pre-2010 version of the public disclosure bar applied if the action were "based upon" the public disclosures. The Seventh Circuit has explained that "this change is not significant," as "[t]he current version of the statute expressly incorporates the 'substantially similar' standard" most circuits applied under the old version. *Bellevue v. Universal Health Servs. of Hartgrove, Inc.*, 867 F.3d 712, 718 (7th Cir. 2017), *petition for cert. filed*, No. 17-842 (U.S. Dec. 7, 2017). Regardless, any difference is irrelevant here, as Relator's allegations are both "based on" and "substantially similar to" the public disclosures.

Cir. 2017) (citation omitted). Ultimately, this part of the test is "'a quick trigger to get to the more exacting original source inquiry.'" *Osheroff*, 776 F.3d at 814 (citation omitted).

In this case, Relators allege the "fraud" is Covance's offering and providing of support services. While Covance disputes that such allegations constitute fraud, Relators' allegations also are substantially similar to the facts previously publicly disclosed. Relators even quote Covance's website as offering the very services it contends lead to Covance's liability. FAC ¶ 21 & nn.11-12. These disclosures illustrate that publication of Covance's services has been widespread, and Relators should not be able to craft an FCA suit from them. As the chart below illustrates, Relator's material allegations can be found on Covance's website (and on Gilead's):

Allegations	**Public Information**
Covance provided "reimbursement support services." FAC ¶ 125.	Covance offers "reimbursement specialists" who can "resolve issues to avoid challenges with limited access" and "support . . . customers with reimbursement or access needs." *Patient Access Programs*, Ex. B.
Covance provided "benefit verification services." FAC ¶ 126.	Covance offers to "verify coverage and cost-sharing obligations"—"Benefits Verification." *Id.*
Covance provided "prior authorization services." *Id.*	Covance offers to "[i]dentify prior authorization requirements to smooth the process for patients and providers"—"Prior Authorization." *Id.*
Covance provided services for "coverage appeals." *Id.*	Covance offers to "[w]ork with payers to identify denial reasons, obtain appeal information and facilitate the appeal process"—"Denials." *Id.*
Covance "marketed the Support Services" to Prescribers. FAC ¶ 127.	Covance advertises a "patient support team" to "engage[] patients and prescribers" and to provide insurance "support services." *Patient Support*, Ex. C.
Covance offered a "reimbursement support team to manage . . . administrative tasks." FAC ¶ 133.	Covance offers "field-based teams . . . to handle patient-specific cases" and "solve access problem and deepen customer relationships." *Field Services*, Ex. D.
Covance used "specialist[s]" to provide support services. FAC ¶ 140.	Covance advertises a "Customer Contact Center" for customers to connect with "reimbursement specialists through a toll-free phone number and optional secure website." *Patient Access Programs*, Ex. B.
Covance field representatives worked with Prescribers in person "if an issue became too complicated, difficult, or time-consuming" to handle over the phone. FAC ¶ 136.	Covance offers "on-site, hands-on help with payer matters, billing, pharmacy interactions, affordability and other issues." *Field Services*, Ex. D.

Allegations	Public Information
Gilead and Covance offered support services for Sovaldi and Harvoni "under a branded program called 'Support Path.'" FAC ¶ 125.	Gilead's Support Path website offers patients "Benefits Investigation" and "Prior Authorization and Appeals Information."[8]
Gilead and Covance marketed and provided support services for Atripla and Truvada. FAC ¶¶ 126, 134.	Gilead's Truvada and Atripla websites[9] offer insurance support and direct patients to Gilead's "Advancing Access" page, which offers benefits verification, prior authorization, and appeals.[10]

The Amended Complaint's other allegations also are substantially similar to publicly disclosed information. Relators took the Medicare summary data directly from ProPublica's website, FAC ¶¶ 185-99 & nn.32-36; in fact, Relators' allegations reproducing that data are *identical* to public information. And they cite two prescribers (to confirm that Covance provides the services it publicly offers), FAC ¶ 183, but ProPublica lists numerous prescribers of Gilead's drugs. *See, e.g.*, *Harvoni Prescriber Checkup*, Ex. F; *Prescriber Checkup*, ProPublica, projects.propublica.org/checkup/providers/1578899845 (listing prescriber in Longview, Texas); *id.*, projects.propublica.org/checkup/providers/1821069162 (listing prescriber in Houston, Texas) (all last visited Feb. 20, 2018).

[8] *Requested Patient Support Path Offerings*, supportpathconsent.iassist.com, attached as Ex. G. Similarly, Gilead's Harvoni website advertises "Insurance Support," offering to "research and verify your benefits," to "explain the prior authorization process and work with your [doctor's] office so they can submit to your insurance company on your behalf," and "to provide assistance if an appeal to your insurance company is required." *Harvoni Support Path, Insurance Support*, www.harvoni.com/support-and-savings/financial-assistance-insurance-support, attached as Ex. H (all last visited Feb. 20, 2018).

[9] *Support & Resources for Patients*, Truvada, www.truvada.com/patients, attached as Ex. I (offering insurance support and directing patients to Gilead Advancing Access); *Support & Resources for Patients*, Atripla, www.atripla.com/co-pay-cost-support, attached as Ex. J (same) (all last visited Feb. 20, 2018).

[10] *Help with Insurance Coverage & Benefits*, Gilead Advancing Access, www.gileadadvancingaccess.com/insurance-support/coverage-benefits, attached as Ex. K (offering to "[r]esearch and assess [patients'] coverage," "Prior Authorization Support," and to help with appeals if coverage has been denied); *Insurance Support for Patients*, Gilead Advancing Access (Providers), www.gileadadvancingaccess.com/hcp/insurance, attached as Ex. L (same) (all last visited Feb. 20, 2018).

Ultimately, Relators' allegations against Covance are substantially similar to the publicly disclosed information, and the public disclosure bar applies. *Fried*, 527 F.3d at 442 (affirming dismissal of FCA claim where "the very essence of the allegations . . . had been publicly disclosed," "[e]ven if [Relator] uncovered some nuggets of new, *i.e.*, non-public, information").

C. Relators Are Not Original Sources

Finally, Relators cannot evade the public disclosure bar under the third part of the test, the "original source" exception. An "original source" is "an individual who either [1] prior to a public disclosure . . . has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based," or [2] "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(B).[11] Relators are neither.

1. Relators Did Not Disclose Information Before The Public Disclosures

The Amended Complaint provides no basis for any argument that Relators satisfy the first definition of "original source"—that they voluntarily disclosed information to the government regarding Covance's support services before Covance publicly discussed its support services on its website. 31 U.S.C. § 3730(e)(4)(B). Relator Green does not allege any knowledge about Covance, and HCA, LLC—which was formed just to bring this lawsuit—provides no facts to infer that it learned of the services before Covance's public advertisements.

[11] The pre-2010 public disclosure bar required "direct and independent knowledge of the information on which the allegations are based." *Colquitt*, 858 F.3d at 374. The Amended Complaint would also fail this version. "'[T]o be "direct," the information must be firsthand knowledge,'" *Fried*, 527 F.3d at 442 (citation omitted). Relators have no firsthand knowledge of the alleged scheme.

2. Relators Do Not Allege Knowledge That Is "Independent Of" And "Materially Adds To" The Public Disclosures, Or That They Disclosed Their Information To The Government Before Filing Suit

Nor do Relators meet the second definition of "original source," which requires them to have knowledge that is "independent of and materially adds to" the public information, and to have provided their information to the government before filing suit. *Id.*; *Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 467 (2007). Relators cannot satisfy any of these three requirements.

(a) *No Disclosure to the Government*

As an initial matter, Relators do not allege or provide any basis to infer that they provided information to the government before filing suit. As such, they cannot be original sources. *See Fed. Recovery Servs.*, 72 F.3d at 452 & n.3 (holding relator, which was incorporated just to bring a *qui tam* action using information from others, was not original source because it failed to show it "provided the information to the Government before filing [the] action") (citation omitted).

(b) *No Independent Knowledge*

Relators also have no "independent" knowledge, which is knowledge "*not* derived from the public disclosure." *Solomon*, 878 F.3d at 147. Relator Green has not alleged *any* knowledge of Covance. She is a former Healthstar employee, and Relators do not allege that she was involved in Scheme Two. *See, e.g.*, FAC ¶ 85. Thus, she has no knowledge regarding Covance, let alone independent, material knowledge.

Nor does HCA, LLC, which merely compiled public information. Relators do not allege that HCA, LLC was involved with Covance, or that it had firsthand knowledge of Covance's alleged fraud. They instead rely on Covance's website, FAC ¶ 21 & nn.11-12, and reproduce data taken from ProPublica's website, FAC ¶¶ 185-99. Relators' reliance on these sources shows they "derived [their] knowledge" from information that was "publically disclosed before [they] filed [the] complaint." *Solomon*, 878 F.3d at 147. Relators do allege that HCA, LLC

interviewed two unnamed Covance employees and employees from other Defendants who were allegedly involved in Scheme Two, but these individuals merely confirmed the information on Covance's website. *See* FAC ¶¶ 134-38, 144. Thus, Relators' "knowledge" is not independent.

(c) *No Material Additions*

Nor does Relators' knowledge materially add to the public disclosures. *Osheroff* addressed this very scenario. There, public websites, advertisements, and a newspaper article disclosed supposed AKS violations. 776 F.3d at 813-14. The relator argued that because he conducted his own investigation and alleged some additional details, he was an original source. *Id.* at 815. The court disagreed. "[B]ackground information that helps one understand or contextualize a public disclosure is insufficient to grant original source status." *Id.* Where the public disclosures are "already sufficient to give rise to an inference that the [defendants] were providing" prohibited remuneration, merely compiling additional details is not enough. *Id.*; *see Fried*, 527 F.3d at 443 (holding that relator failed to show that his allegations were "'qualitatively different information than what had already been discovered' and not merely the 'product and outgrowth' of publicly disclosed information") (citation omitted).

So too here. Neither HCA, LLC nor Green has personal knowledge of requisite details. The limited hearsay allegations from former employees cited in the Amended Complaint are covered by the public information. *Compare* FAC ¶ 144 (alleging former employee "explained that field reps' responsibilities include[d] . . . helping staff complete and prepare insurance forms, communicating with Covance's reimbursement support call center employees, and helping to resolve any and all coverage issues"), *with Patient Access Programs*, Ex. B (offering the same services), *and Field Services*, Ex. D (same). To be sure, the employees allegedly "confirmed that [the] pitch" for Gilead's Covered Drugs "included an offer to outsource Support Services." FAC ¶ 134. But that only shows Relators are not original sources: *confirming* public

information, by definition, does not *materially add* to it. *See Confirm*, Black's Law Dictionary (10th ed. 2014) (defining "confirm" as "[t]o verify or corroborate").

The same is true regarding the remaining allegations. Relators cite two anonymous alleged "Prescribers" as having utilized some support services (although they provide no details regarding what services were used, when they were used, how they were used, or for whom they were used). FAC ¶ 183. But ProPublica's website lists hundreds of prescribers of Gilead's drugs. *See Harvoni Prescriber Checkup*, Ex. F; *Sovaldi Prescriber Checkup*, ProPublica, projects.propublica.org/checkup/drugs/8477 (last visited Feb. 20, 2018), attached as Ex. M. Listing two anonymous prescribers is hardly a material addition, given that (i) Covance's website publicizes its provision of support services, (ii) Gilead's websites for all four drugs publicly offer support services to patients and doctors, and (iii) ProPublica publicly disclosed numerous prescribers. As for the Medicare summary data, Relators took it directly from public sources, and thus cannot claim to have "materially add[ed]" to it.

In the end, anyone could find the Relators' material allegations against Covance through a quick Google search. As such, these allegations are based on public information, Relators are not "original sources," and the public disclosure bar precludes their FCA claims.

III. Relators Fail To Plead Fraud With Particularity Under Rule 9(b)

The Court should also dismiss the Amended Complaint because Relators fail to plead fraud with particularity as required by Fed. R. Civ. P. 9(b).

A. Relators Must Plead Fraud With Particularity

Rule 9(b) is "'a gatekeeper to discovery [and] a tool to weed out meritless fraud claims sooner than later.'" *Webb v. Everhome Mortg.*, 704 F. App'x 327, 330 (5th Cir. 2017) (per curiam) (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009)). Thus, the Fifth Circuit has long required FCA relators to "set forth the 'who, what, when, where, and

how' of the alleged fraud." *U.S. ex. rel. Spicer v. Westbrook*, 751 F.3d 354, 365 (5th Cir. 2014) (citation omitted). Where relators make only generalized allegations without the "'*particular* details of a scheme,'" dismissal is appropriate. *Nunnally*, 519 F. App'x at 895 (citation omitted). *See U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 47 (1st Cir. 2009) ("[I]t is the fraud itself which must be pled with particularity, not just who benefits from the fraud and what pot of federal money may be the object of the fraud."); *U.S. ex rel. Hebert v. Dizney*, 295 F. App'x 717, 723 (5th Cir. 2008) (affirming dismissal where Relator's "generalized allegations [did] not come close to satisfying Rule 9(b)"). Critically, a complaint, like the 370-paragraph complaint filed here, "can be long-winded, even prolix, without pleading with particularity." *Williams v. WMX Techs., Inc*., 112 F.3d 175, 178 (5th Cir. 1997) (dismissing fraud claims on Rule 9(b) grounds).

Particularity takes on even more importance where a relator alleges that a third party, rather than the defendant, submitted the allegedly false claims for payment. Indeed, when "allegations include a long chain of causal links from defendants' conduct to the eventual submission of claims," "Rule 9(b) requires relators to adequately allege the entire chain—from start to finish—to fairly show defendants caused false claims to be filed." *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017). Courts therefore dismiss FCA claims where the relator pleads only one link in the causal chain, then "jumps to a number of unsubstantiated conclusions." *U.S. ex rel. Foster v. Bristol-Myers Squibb Co.*, 587 F. Supp. 2d 805, 824 (E.D. Tex. 2008). In *Nunnally*, for example, the Fifth Circuit affirmed the dismissal of an AKS-based FCA claim against a hospital where the relator failed to plead "the identity of any physicians [or] actual inducements," "any particular details of any actual referral by a physician," or any "particularity [regarding] an actual certification to the Government that was a prerequisite to obtaining the government benefit." 519 F. App'x at 894.

Further, the FCA "'attaches liability . . . to the claim for payment,'" not the underlying scheme. *Spicer*, 751 F.3d at 364-65 (citation omitted). Thus, while "the details of an actually submitted false claim" need not always be alleged, *Grubbs*, 565 F.3d at 190, relators must present "reliable indicia that false bills were actually submitted as a result of the scheme," *id.* at 189. That is, they must allege "details leading to a strong inference that [false] claims were submitted—such as dates and descriptions of . . . services and a description of the billing system that the records were likely entered into." *Id.* at 190-91. Of course, FCA complaints still fail if they do not "allege the details of the scheme with sufficient particularity," even if they contain reliable indicia that false claims were submitted. *Colquitt*, 858 F.3d at 372. For example, the Fifth Circuit has affirmed dismissal of an FCA complaint that alleged a hospital submitted "thousands of [illegal] claims," costing Medicare billions, because it made "wholly generalized allegations of false claims presented to the Government." *Nunnally*, 519 F. App'x at 894, 895.

B. Relators Fail To Plead The Fraudulent Scheme With Particularity

Here, Relators fail to plead the who, what, when, where, or how of an allegedly complex, multi-link fraudulent scheme. When discussing Medicare, for example, Relators appear to theorize that: (1) Gilead and Covance communicated the availability of support services for patients; (2) Gilead and Covance provided support services to patients who were prescribed Gilead's drugs; (3) doctors were thus induced to prescribe Gilead's drugs; (4) patients filled their prescriptions; and (5) pharmacies submitted accordant claims to the government for payment. FAC ¶¶ 44-46. Relators' Amended Complaint fails to provide sufficient detail at every step.

Instead, it generally alleges Covance offered support services, "then jumps to a number of unsubstantiated conclusions." *Foster*, 587 F. Supp. 2d at 824. It provides little detail regarding doctors who allegedly benefitted from support services. At best, it cites two unnamed prescribers who allegedly used some services, FAC ¶ 183, but it provides no details on what

services were used, when they were used, how they were used, or for whom they were used.[12] *See Colquitt*, 858 F.3d at 372 (affirming dismissal of AKS-based FCA claim on Rule 9(b) grounds where "[n]o particulars" were alleged to connect "the unidentified doctors who received the ill-defined benefits" to the alleged false claims). Indeed, the Amended Complaint does "not list one instance," nor any "factual detail or example," to show that Covance's services caused doctors to prescribe Gilead's drugs "over [those] of a competitor." *Foster*, 587 F. Supp. 2d at 824; *see Nunnally*, 519 F. App'x at 894 (affirming dismissal of AKS-based FCA claim where relator failed to plead "actual inducements" or "improper referrals").

The Amended Complaint provides even less detail for the rest of the causal chain. It does not connect doctors to patients or describe any patients who received prescriptions, "much less show that the patient[s were] connected to Medicaid" or another government payer. *Foster*, 587 F. Supp. 2d at 824. It does not identify which pharmacies filled prescriptions. It does not describe when, how, or to whom doctors or pharmacies submitted requests for payment. It does not even distinguish between private and government insurers, *see, e.g.*, FAC ¶ 140—even though the FCA requires the submission of false claims *to the government*. And the Medicare summary data, FAC ¶¶ 185-99, says nothing about whether any claims were false because they "result[ed] from a violation of" the AKS. 42 U.S.C. § 1320a-7b(g). *See U.S. ex rel. Booker v. Pfizer*, 847 F.3d 52, 58 (1st Cir. 2017) (rejecting "aggregate data reflecting the amount of money expended by Medicaid for" the defendant's drugs as insufficient to support inference that false claims were submitted); *see U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). Thus, the Amended Complaint neither alleges the scheme with particularity nor provides reliable indicia that false claims were actually submitted to the

[12] The Amended Complaint cites no prescribers who prescribed Truvada or Atripla. *Id.*

government for payment. *See U.S. ex rel. Gage v. Davis S.R. Aviation, L.L.C.*, 623 F. App'x 622, 625, 627 (5th Cir. 2015) (affirming FCA dismissal where relator did "not plead with particularity *what* was false about the claims," "*how* they were false," or "*when* and *where* defendants made false claims"); *U.S. ex rel. Chase v. HPC Healthcare, Inc.*, No. 16-16670, 2018 WL 526039, at *3-4 (11th Cir. Jan. 24, 2018) (affirming FCA dismissal where complaint gave no examples and lacked reliable indicia to show that actual false claims were submitted).

To be sure, the Amended Complaint spends dozens of paragraphs explaining how federal insurance programs work. FAC ¶¶ 41-82. But describing Medicare or Medicaid in general terms is not enough to plead a complex, multi-link fraudulent scheme with particularity. Even though Scheme Two allegedly "encompasse[d] every Prescriber that, since at least 2013, received Support Services from Covance," FAC ¶ 179, the Amended Complaint provides almost no specifics, and fails to connect even the two anonymous prescribers it cites to prescriptions, patients, pharmacies, or claims submitted to the government for payment. *See U.S. ex rel. Hagerty v. Cyberonics, Inc.*, 95 F. Supp. 3d 240, 266 (D. Mass. 2015) (dismissing FCA claim that "only identifie[d] a single patient, a single physician, and a [few] facilities where fraudulent activity may have occurred, and which therefore may have led to the filing of false claims").

At bottom, the Amended Complaint makes a series of assumptions that cannot satisfy Rule 9(b): that Covance illegally induced unnamed doctors to prescribe unidentified drugs over unspecified competing drugs; that unidentified patients were enrolled in unspecified government (not private) insurance programs and used some form of Covance's support services; that these patients took prescriptions to unnamed pharmacies who filled them; and that these pharmacies submitted false claims for payment to the government. Rule 9(b) does not permit such vague pleading. *See Cooper v. Pottstown Hosp. Co. LLC*, 651 F. App'x 114, 117 (3d Cir. 2016)

(dismissing AKS-based FCA claim because simply "attaching conclusory labels to ordinary, lawful acts of business does not suffice"). As such, Relators have not met their burden under Rule 9(b), and the Amended Complaint's claims against Covance should be dismissed.

C. Relators Do Not Allege Covance Was Involved In Schemes One Or Three

To the extent Relators belatedly attempt to implicate Covance in Schemes One or Three, Rule 9(b) prohibits such a claim. "[A] complaint must plead fraud with particularity as to each defendant." *McNamara v. Bre-X Minerals Ltd.*, 57 F. Supp. 2d 396, 427 (E.D. Tex. 1999). Specifically, "Plaintiffs must distinguish among defendants and allege the role of each" for the claimed fraud. *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 287 (5th Cir. 2006); *see Unimobil 84, Inc. v. Spurney*, 797 F.2d 214, 217 (5th Cir. 1986). Courts should dismiss fraud claims under Rule 9(b) where plaintiffs make "general allegations, which lump all defendants together" and "fail[] to segregate the alleged wrongdoing of one from those of another." *In re Urcarco Sec. Litig.*, 148 F.R.D. 561, 569 (N.D. Tex. 1993), *aff'd*, *Melder v. Morris*, 27 F.3d 1097 (5th Cir. 1994).

Here, the Amended Complaint fails to allege with particularity that Covance was involved in Schemes One or Three. Instead, it separates the Defendants for three separate purported "schemes." *See* FAC ¶¶ 4, 90-124 (alleging Gilead carried out Scheme One with Healthstar); FAC ¶¶ 6, 152-76 (same for Scheme Three). Thus, Relators contradict their general assertion that these were "three intertwined, unlawful marketing schemes." FAC ¶ 3.

Given these allegations, a single, passing mention is insufficient to implicate Covance in Scheme Three. *See* FAC ¶ 156. For one thing, a lone mention fails to plead *with particularity* that Covance participated in that scheme, as the Amended Complaint provides no specifics on how Covance was involved. For another, the Amended Complaint repeatedly confirms that only Gilead and Healthstar participated in Schemes One and Three. *See, e.g.*, FAC ¶¶ 4, 6, 87, 89.

And if there were any doubt, the Amended Complaint cites Covance employees *only* when discussing Scheme Two. *Compare* FAC ¶ 85 (noting that CI-6 and CI-11 worked for Covance), *and* FAC ¶¶ 134-36, 144, 146 (citing CI-6 and CI-11 for Scheme Two), *with* FAC ¶ 85 (noting that CI-1, CI-2, CI-3, CI-4, and Green worked for Healthstar), FAC ¶¶ 103, 106-08, 111-14, 119-23 (citing CI-1, CI-2, CI-3, CI-4, and Green for Scheme One), *and* FAC ¶¶ 157, 160-68, 174-75 (same for Scheme Three). Given that the Amended Complaint fails to allege Covance was involved, the Court must dismiss any claims against Covance based on Schemes One or Three.

IV. Alleged Medicare Regulatory Violations Are Unrelated To The AKS Or The FCA

Nor can Relators save their claims by relying upon alleged violations of Medicare regulations requiring Part D sponsors to create programs for coverage determinations. *See* FAC ¶¶ 146-51. The Amended Complaint alleges that, while providing support services, "Covance [employees] violated Medicare regulations regarding patient privacy and duty of care" by misrepresenting that they had the authority to act on behalf of patients. FAC ¶ 146. Covance employees would allegedly contact insurers and say they were "calling at the request of the doctor's office and on behalf of the patient." *Id.* (emphasis omitted). Relators allege that these statements misrepresented Covance's role, as Covance was "neither a patient's 'appointed representative' nor 'calling from the doctor's office.'" FAC ¶ 147.

Relators lack standing to bring such a claim. The Centers for Medicare & Medicaid Services, not private litigants, enforce these regulations. *See* 42 C.F.R. §§ 423.168(d), 423.509, 423.750. They contain no private right of action. *Stewart v. Bernstein*, 769 F.2d 1088, 1092 n.6 (5th Cir. 1985) ("[F]ederal regulations cannot themselves create a cause of action; this is a job for the legislature."). Nor do they support Relators' theory of liability, which is that Covance violated the FCA *by violating the Anti-Kickback Statute*. FAC ¶ 145. Whether Covance had the

"legal authority" to seek coverage determinations for patients, FAC ¶ 151, has nothing to do with whether the support services themselves were purportedly illegal kickbacks.

To that point, Relators do not even argue that the alleged regulatory violations relate to the AKS or the FCA. They say only that Covance's conduct "raises significant privacy and patient care concerns." *Id.* But "[t]he False Claims Act is not 'an all-purpose antifraud statute'" or "a vehicle for punishing garden-variety . . . regulatory violations." *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 2003 (2016) (citation omitted); *see U.S. ex rel. Gudur v. Deloitte & Touche*, No. 07-20414, 2008 WL 3244000, at *2 (5th Cir. Aug. 7, 2008) (per curiam) ("The FCA is . . . not the appropriate vehicle for policing regulatory compliance.").

And even if Relators could bring such a claim in theory, they fail to allege wrongdoing. Taking the allegations at face value, Covance employees called *at the request* of a doctor or *on behalf* of a patient. FAC ¶ 146. That does not violate the regulations, which permit patients and their doctors to seek coverage determinations. 42 C.F.R. § 423.566(c). As for the notion that Covance employees were not patients' "appointed representative[s]," *id.*, Relators make a lone allegation that Covance did not "follow [the] rules" for appointing representatives. FAC ¶ 151. Such a conclusory allegation fails to state a claim, let alone plead fraud with particularity as required by Rule 9(b). *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009) ("[T]he conclusory nature of [these] allegations . . . disentitles them to the presumption of truth."). In sum, the Court should dismiss any claim based on these alleged regulatory violations.

V. Relators Fail To State A Claim Under The State-Law Analogues

Counts 4-34, which allege that Covance violated the false claims statutes of thirty-one States, fail for the same reasons the federal FCA claims fail. As with the federal FCA, each state false claims statute Relators cite requires a false claim or a material false statement, and each contains a public disclosure bar. *See* App'x 1 (listing state false claims statutes, qui tam

provisions, and corresponding public disclosure bars). Thus, Counts 4-34 must be dismissed for the same reasons as Counts 1-3. *See Ruscher*, 663 F. App'x at 371, 377 (affirming dismissal of claims under state false claims statutes where federal FCA claims failed); *Foster*, 587 F. Supp. 2d at 827-28 (same). Moreover, these claims fail under Rule 9(b) because Relators fail to allege specific acts committed in these states. *See U.S. ex rel. Ribik v. HCR ManorCare, Inc.*, No. 1:09-cv-13, 2017 WL 3471426, at *3 (E.D. Va. Aug. 10, 2017), *appeal filed*, No. 17-2069 (4th Cir.).

Relators also attempt to assert counts under state statutes they lack standing to enforce. Arkansas's false claims statute (Count 4), for example, **does not even permit *qui tam* actions**. *See* Ark. Code Ann. §§ 20-77-901 – 911. Maryland's statute (Count 17) requires courts to "dismiss the action" if, as here, "the State does not elect to intervene." Md. Gen. Provis. § 8-104(a)(7). New Mexico's statute (Count 25) limits *qui tam* actions to "affected persons" and, when the State declines to intervene, permits relators to proceed only if the State finds there is "substantial evidence" of a violation. N.M. Stat. § 27-14-7(B), (E)(2). Relators provide no basis to satisfy either requirement.[13] Nor can they satisfy New Hampshire's statute (Count 23), which prohibits *qui tam* actions unless the defendant "has its principal place of business within the state" or received a threshold level of reimbursement from New Hampshire's Medicaid program. N.H. Rev. Stat. § 167:61-c(II)(a). These independent grounds also require dismissal.

VI. Relators Fail To State A Claim For An FCA Conspiracy

In addition to the defects that doom all of Relators' FCA claims, Count 3 (the conspiracy claim) fails for the independent reason that Relators do not allege a conspiracy to violate the

[13] *See U.S. ex rel. King v. Solvay S.A.*, 823 F. Supp. 2d 472, 520-21 (S.D. Tex. 2011), *vacated in part on other grounds*, No. 06-2662, 2012 WL 1067228 (Mar. 28, 2012); *U.S. ex rel. Streck v. Allergan, Inc.*, 894 F. Supp. 2d 584, 604 (E.D. Pa. 2012), *appeal filed*, No. 17-1014 (3d Cir.). The New Mexico Fraud Against Taxpayers Act does not contain these limitations. *King*, 823 F. Supp. 2d at 520 n.24.

False Claims Act. To sustain a claim under the FCA's conspiracy provision, relators must "plead facts showing that there was a plan or agreement *'to commit a violation of' one or more of the FCA subsections*." *Ibanez*, 874 F.3d at 917 (quoting 31 U.S.C. § 3729(a)(1)(C)) (emphasis added); *see U.S. ex rel. Farmer v. City of Houston*, 523 F.3d 333, 343-44 (5th Cir. 2008).[14] They must "do more than point to a possibility of an agreement" to violate the FCA. *Grubbs*, 565 F.3d at 194. Nor is it "enough for relators to show there was an agreement that made it *likely* there would be a violation of the FCA." *Ibanez*, 874 F.3d at 917. Rather, relators "must show an agreement was made *in order to* violate the FCA." *Id.* And they must plead the agreement "'with particularity'" under Rule 9(b). *Grubbs*, 565 F.3d at 193 (citation omitted).

Relators have failed to do so. While the Amended Complaint generally alleges that "Gilead conspired with Gilead's co-Defendants, physicians, and other health care professionals" to violate the AKS (and so the FCA), FAC ¶ 213, it "fails to identify a specific statement where [Defendants] agreed to defraud the government." *U.S. ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 27 (2d Cir. 2016). Thus, the Court should dismiss Relators' conspiracy claim.[15]

CONCLUSION

For the foregoing reasons, Covance respectfully asks this Court to dismiss the Amended Complaint's claims against it with prejudice.[16]

[14] Before 2009, the FCA used different language, but "[t]his difference is inconsequential." *Spicer*, 751 F.3d at 361 n.8.

[15] Further, because the claim is "premised on . . . underlying FCA violations," it "rises and falls with [those] claims." *U.S. ex rel. Godfrey v. KBR, Inc.*, 360 F. App'x 407, 413 (4th Cir. 2010) (per curiam).

[16] The Court should dismiss the Amended Complaint without leave to amend, as any amendment would be futile. *See Briggs v. Mississippi*, 331 F.3d 499, 508 (5th Cir. 2003).

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Respectfully submitted,

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Appendix 1: State False Claims Statutes

State	False Claim Statute	Qui Tam Provision	Public Disclosure Bar
Arkansas (Count 4)	No qui tam provision, Ark. Code §§ 20-77-901 – 911		
California (Count 5)	Cal. Gov't Code § 12651	§ 12652(c)	§ 12652(d)(3)
Colorado (Count 6)	Colo. Rev. Stat. § 25.5-4-305	§ 25.5-4-306(2)	§ 25.5-4-306(5)(c)
Connecticut (Count 7)	Conn. Gen. Stat. § 4-275	§ 4-277(a)	§ 4-282(b)
Delaware (Count 8)	Del. Code Tit. 6 § 1201	§ 1203(b)	§ 1206
D.C. (Count 9)	D.C. Code § 2-381.02	§ 2-381.03(b)	§ 2-381.03(c-1)
Florida (Count 10)	Fla Stat. § 68.082	§ 68.083(2)	68.087(3)
Georgia (Count 11)	Ga. Code § 49-4-168.1	§ 49-4-168.2(b)	§ 49-4-168.2(l)
Hawaii (Count 12)	Haw. Rev. Stat. § 661-21	§ 661-25(a)	§ 661-31
Illinois (Count 13)	740 Ill. Comp. Stat. § 175/3	§ 175/4(b)	§ 175/4(e)(4)
Indiana (Count 14)	Ind. Code § 5-11-5.5-2	§ 5-11-5.5-4(a)	§ 5-11-5.5-7(f)
Iowa (Count 15)	Iowa Code § 685.2	§ 685.3(2)	§ 685.3.5.c
Louisiana (Count 16)	La. Stat. § 46:438.3	§ 46:439.1(A)	§ 46:439.1(D)
Maryland (Count 17)	Court must dismiss if State does not intervene, Md. Gen. Provis. § 8-104(a)(7); Md. Code Health-Gen. § 2-604(a)(7).		
Massachusetts (Count 18)	Mass. Gen. Laws Ch. 12 § 5B	§ 5C(2)	§ 5G(c)
Michigan (Count 19)	Mich. Comp. Laws §§ 400.603, 400.606, 400.607	§ 400.610a(1)	§ 400.610a(13)
Minnesota (Count 20)	Minn. Stat. § 15C.02	§ 15C.05(a)	§ 15C.05(f)
Montana (Count 21)	Mont. Code Ann. § 17-8-403(1)	§ 17-8-406(1)	§ 17-8-403(6)
Nevada (Count 22)	Nev. Rev. Stat. § 357.040	§ 357.080(1)	§ 357.100
New Hampshire (Count 23)	N.H. Rev. Stat. § 167:61-b(I)	§ 167:61-c(II)	§ 167:61-e(III)
New Jersey (Count 24)	N.J. Stat. § 2A:32C-3	§ 2A:32C-5(b)	§ 2A:32C-9(c)

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State	False Claim Statute	Qui Tam Provision	Public Disclosure Bar
New Mexico (Count 25)	N.M. Stat. § 27-14-4; § 44-9-3	§ 27-14-7(B); § 44-9-5(A)	§ 27-14-10(C); § 44-9-9(D)
New York (Count 26)	N.Y. State Fin. Law § 189(1)	§ 190(2)	§ 190(9)(b)
North Carolina (Count 27)	N.C. Gen. Stat. § 1-607	§ 1-608(b)	§ 1-611(d)
Oklahoma (Count 28)	Okla. Stat. Tit. 63 § 5053.1(B)	§ 5053.2(B)	§ 5053.5(B)
Rhode Island (Count 29)	R.I. Gen. Laws § 9-1.1-3(a)	§ 9-1.1-4(b)	§ 9-1.1-4(e)(4)
Tennessee (Count 30)	Tenn. Code. § 4-18-103; § 71-5-182	§ 4-18-104(c); § 71-5-183(b)	§ 4-18-104(d)(3); § 71-5-183(e)(2)
Texas (Count 31)	Tex. Hum. Res. Code § 36.002	§ 36.101(a)	§ 36.113(b)
Vermont (Count 32)	Vt. Stat. Tit. 32 § 631(a)	§ 632(b)	§ 636(c)
Virginia (Count 33)	Va. Code § 8.01-216.3	§ 8.01-216.5(A)	§ 8.01-216.8
Washington (Count 34)	Wash. Rev. Code § 74.66.020	§ 74.66.050(1)	§ 74.66.080(2)

CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of February, 2018, I filed the foregoing with the Clerk of the United States District Court using the CM/ECF system, which will send notification electronically to all counsel of record.

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